REMARKS

Status of the Claims

Claims 11-20, 22, 23, and 26-38 are pending in the application. Claims 21, 24-25 were previously cancelled. Applicant hereby cancels claims 19 and 29 for being duplicative of other claims. Claims 27 and 33-38 were previously withdrawn pursuant to a restriction requirement. Claims 11-18, 26, 30-32 are hereby amended. Support for the amendments to independent claims 11 and 18 may be found in the specification and claims as originally filed, and particularly, paragraph [0004], [0005], [0006], and [0007]. Additional support for the amendments to the claims may be found in the specification, for example, in Figure 1 and accompanying text such as paragraphs [0017], [0018], and [0023]. Other minor formatting changes have been made. No new matter is added by the changes.

Claim Objection

Claim 29 is objected to because it appears to the Examiner to be a duplicate of Claim 28. In response, Applicant has cancelled claim 29.

Rejection Under 35 U.S.C. §102(b) on the Basis of SCHWARTZ-FELDMAN

The Examiner has rejected Claims 11, 17, and 31-32 as being unpatentable under 35 U.S.C. §102(b) on the basis of Schwartz-Feldman (US Patent No. 5,501,371) ("SCHWARTZ-FELDMAN"). This rejection is respectfully traversed in light of the amendments to Claim 11, noting also that Claims 17, 31 and 32 depend from Claim 11 directly or indirectly.

For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co*., 868 F.2d 1226, 1236; 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304; 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978).

SCHWARTZ-FELDMAN does not teach or suggest each and every element of the invention as currently claimed. In particular, SCHWARTZ-FELDMAN does not teach or suggest: a delivery system comprising an injector system coupled to a driving system, the injector system comprising: a housing defining a lumen and having an output end and a driving

system connection end, the lumen comprising a proximal portion and a distal portion and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion; a needle assembly coupled to the output end of the housing for coupling to a needle; and ***a mixing member extending through the lumen from the driving system connection end to at least a portion of the needle assembly***, the mixing member being rotatable within the lumen in both the proximal portion and the distal portion; and

the driving system comprises:

a drive mechanism;

an actuator coupled to the drive mechanism to actuate the drive mechanism; and a

rotatable interfacing member coupled to the drive mechanism for coupling with the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism, wherein the ***mixing member is rotatable and mixing occurs in the needle assembly and the lumen***. (emphasis added).

Independent Claim 11, as currently amended, claims that the mixing member extends into the needle assembly and is rotatable in the needle assembly. This is simply not taught by SCHWARTZ-FELDMAN.

SCHWARTZ-FELDMAN is missing certain elements of the invention as claimed. It does not teach or suggest ***a mixing member that extends into the needle assembly***, especially where a mixing member is rotatable in the needle assembly. The Examiner attempts to argue otherwise, but the Figures of SCHWARTZ-FELDMAN clearly show that there is no mixing member in the needle assembly.

Moreover, SCHWARTZ-FELDMAN does not teach a ***mixing member which is rotatable and wherein mixing occurs*** in the needle assembly. End portion 140a, which the Examiner cites as purportedly showing that the mixing member extends into the needle assembly, is ***not*** a part of the mixing means of SCHWARTZ-FELDMAN's device, but rather, is a member that is attached to the casing ("mixing cylinder" 102) that holds the mixing means. The "end portion 140a" referred to by the Examiner refers to one of four "planar flanges 140a, b, c, and d" that is distal to the mixing mechanism taught in SCHWARTZ-FELDMAN. ("Distal point 130 includes an annular beveled valve surface 138 and a plurality of ***planar flanges 140a, b, c, and d*** radially positioned about the center axis of cylindrical body 120. Planar flanges 140a,

b, c, and d include an upper positioning tab 142a, b, c, and d and a lower stop tab 144a, b, c, and d;" col. 3, lines 62-67) (see col. 4, lines 57-60, which explains how the positioning tabs on the planar flanges help to affix a valve 138 that prevents inadvertent leakage of materials during the mixing action).

This is illustrated in Figures 1 and 7-9 of SCHWARTZ-FELDMAN which show that mixing would occur in the "cylindrical body 120" of the mixer cylinder 102 and ***not in the distal point 130***. As shown in these figures in SCHWARTZ-FELDMAN, the mixing means 26 is proximal to, and ***does not extend into, the tapered tip 84*** (which the Examiner incorrectly construes as reading upon the claimed "needle assembly").

That is, mixing occurs by a "mixing means 26 compris[ing] a paddle mixer 100 and a paddle mixer cylinder 102. Paddle mixer includes a circular planar head 104, a stem 106, and a plurality of paddle blades 108a, b, and c. Circular planar head 104 includes a plurality of notches 110a, b, c, and d for spatially coinciding with, and mechanically engaging the plunger inner ribs 66a, b, c, and d respectively." (SCHWARTZ-FELDMAN, col. 3, lines 36-49).

The actual mixing that occurs in the operation of the device is illustrated in sequential steps in Figures 7-10. "The mixing process is initiated by partially retracting paddle blades 108a, b, and c through the process of rotating plunger 50 as depicted in FIG. 7. Plunger inner ribs 66a, b, c, and d are mechanically engaged to notches 110a, b, and c, transmitting the twisting motion placed on plunger 50 to paddle mixer 100…Continued rotation of plunger 50 results in a *spinning motion of mixing means 26 about the long axis of paddle mixer 100.* (col. 4, lines 33-42). ***The spinning motion does not further extend distally from the distal tip of the paddle mixer 100*** and thus, mixing does not occur in the tapered tip

As illustrated above, since SCHWARTZ-FELDMAN is lacking features of the claimed invention, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under §102(b) over SCHWARTZ-FELDMAN. Claim 17 is dependent directly on claim 11, and the rejection of that claim fails at least because of the fundamental defect discussed above.

Rejection Under 35 U.S.C. §102(b) on the Basis of HICKS

The Examiner has rejected Claims 18-20, 22-23 and 28-30 under 35 U.S.C. §102(b) on the basis of Hicks (US Patent No. 2,825,134) ("HICKS"). This rejection is respectfully traversed under the standard recited above.

HICKS does not teach or suggest each and every feature of the invention. Further, HICKS does not teach or suggest: a coupling system for use with a tube of a syringe comprising: a housing for coupling to the tube of the syringe, said syringe comprising a needle assembly coupled to an output end of the tube; a drive mechanism disposed within the housing; a mixing member for coupling to the drive mechanism, extending into the tube of the syringe and being ***rotatable within the tube of the syringe*** in both the proximal portion and the distal portion ***and at least a portion of the needle assembly*** to mix and deliver an injectable from the tube of the syringe; and an actuator coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member ***and mixing occurs in the needle assembly and the tube.***

Independent Claim 18, as amended, claims that the mixing member is rotatable into at least a portion of the needle assembly and mixing occurs in the needle assembly and the tube. In contrast, as stated by the Examiner herself, HICKS "disclose[s] in FIG 1 [that] the mixing member 24 extends ***within*** the tube of the syringe and rotates ***within*** the tube of the syringe." Mixing only occurs within the tube. As such, HICKS fails to teach all of the claimed features and thus, does not anticipate the claimed invention.

Thus, the rejection under §102(b) should be withdrawn.

Rejection Under 35 USC 103(a) Based on SCHWARTZ-FELDMAN in View of CRITCHLOW

The Examiner has rejected Claims 12-16 as being unpatentable over SCHWARTZ-FELDMAN in view of Critchlow et al (U.S. Patent Application Number 2003/0171712) ("CRITCHLOW") and also makes mention of HICKS without a specific listing in the list of citations for these claims. This rejection is respectfully traversed.

This rejection is traversed for the reasons discussed above. In order to sustain an obviousness rejection, the differences between the subject matter sought to be patented and the

prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007), quoting *In re Kahn* , 441 F.3d 977, 988, (Fed. Cir. 2006). In addition, there must be a reasonable expectation of success. *See* MPEP 2143.02.

Additionally, the Examiner's attempt to combine SCHWARTZ-FELDMAN with CRITCHLOW is not supportable. The Examiner notes that SCHWARTZ-FELDMAN does not teach or suggest a low torque motor, a battery or a switch. The Examiner fails to note that SCHWARTZ-FELDMAN also does not teach or suggest a mixing member that extends into the needle assembly, especially where a mixing member is rotatable and mixing occurs in the needle assembly.

Additionally, SCHWARTZ-FELDMAN does not teach or suggest the drive mechanism as currently claimed. CRITCHLOW does not teach or suggest:

a mixing member being rotatable within the lumen in both the proximal portion and the distal portion

or

a mixing member rotatable and wherein mixing occurs in the needle assembly.

Thus, the combination of SCHWARTZ-FELDMAN and CRITCHLOW does not result in the invention.

The Examiner's attempt to add HICKS to the combination of SCHWARTZ-FELDMAN and CRITCHLOW also fails for the reasons described above, especially since (as previously explained) HICKS teaches away from the use of

a mixing member rotatable in the needle assembly.

Thus, for the reasons explained above, withdrawal of the rejection under 35 USC 103(a) is respectfully requested.

Rejection Under 35 USC 103(a) Based on SCHWARTZ-FELDMAN in View of BARKER

The Examiner has rejected Claim 26 as being unpatentable over SCHWARTZ-FELDMAN in view of Barker et al (US Patent No. 6,033,105) ("BARKER"). This rejection is respectfully traversed.

This rejection is traversed for the reasons discussed above. Additionally, BARKER's technology is directed to bone cement and requires ***2 chambers***, one for mixing and one for delivery. Its relevance to Claim 26 is not understood and its combination with SCHWARTZ-FELDMAN is not supportable. *A needle assembly* is not remotely related to BARKER, much less *a needle assembly with a mixing member rotatable therein.*

Thus, for the reasons explained above, withdrawal of the rejection under 35 USC 103(a) is respectfully requested.

Conclusion

In light of the foregoing remarks, applicants believe that all rejections of record have been obviated, and allowance of this application is respectfully requested. An early Notice of Allowance or Advisory Action, if appropriate, is solicited. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

Respectfully submitted,

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